PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Art Unit: 3734
Atsushi OGAWA, et al.	Examiner: Diane D. Yabut
Serial No: 10/539,662	
Confirmation No. : 6654	
Filed: June 14, 2005	
For: INDWELLING IMPLANT FOR EMBOLIZATION	

REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is a Reply Brief in response to the Examiner's Answer dated April 23, 2009 and is directed to the Appeal from the Examiner's Final Rejection of Claims 1-8 in the Office Action dated November 28, 2007. The Notice of Appeal from the Final Rejection was filed on April 28, 2008. This Reply Brief replaces the original Appeal Brief and is directed to the new ground of rejection set forth in the Examiner's Answer and the grounds of rejection set forth in the Final Office Action.

REAL PARTY IN INTEREST

The real parties in interest are Kaneka Corporation and Kaneka Medix Corporation, the assignees of record.

RELATED APPEALS AND INTERFERENCES

Applicant is not aware of any other appeal or interference that will affect the outcome of this appeal, will have a bearing on this appeal or will be affected by the outcome of this appeal.

STATUS OF CLAIMS

Claims 1-8 are pending and rejected. This Appeal is directed to the rejection of Claims 1-8.

STATUS OF AMENDMENTS

An Amendment After Final Action was filed January 24, 2008, in response to the Final Office Action of November 28, 2007, presenting arguments with no claim amendments. The After Final Amendment dated January 24, 2008 has been entered. This Appeal is based on the Claims as presented in the Amendment of September 13, 2007.

SUMMARY OF CLAIMED SUBJECT MATTER

Claims 1 and 8 are independent.

Claim 1 is directed to an indwelling implant for embolization including a coil composed of a metal and a substantially semispherical rounded head portion at the distal end portion of the coil *(See, Specification at Page 8, lines 9-24 and Page 4, lines 7-18).* A single closed loop is provided inside the coil from the head portion toward the proximal end portion of the coil *(See, Specification at Figs. 1 and 2 and at Page 10, lines 1-5).* An axial extension controlling member composed of at least one wire material which is thinner than the metal wire material forming the loop is provided inside the coil by extending the member in the coil axial direction of the coil and fixing both ends thereof directly or indirectly to the proximal end portion after the member passed through the loop *(See, Specification at Figs. 1 and 2, Page 10, lines 5-17 and Page 4, lines 19-27).* The single closed loop is directly fixed to the rounded head portion and directly coupled to the axial extension controlling member *(See, Specification at Figs. 1 and 2 and at Page 10, lines 1-5).*

Claim 2 is directed to an indwelling implant as set forth in Claim 1. The axial extension controlling member and loop are composed of the same metal material as the coil *(See, Specification at Page 5, lines 5-10).*

Claim 3 is directed to an indwelling implant as set forth in Claim 1. The coil is composed of platinum or a platinum alloy *(See, Specification at Page 5, lines 5-10).*

Claim 4 is directed to an indwelling implant as set forth in Claim 3. The axial extension controlling member is composed of a wire material with a diameter of 20 μm or less *(See, Specification at Page 10, line 5-7 to Page 12, line 3).*

Claim 5 is directed to an indwelling implant as set forth in Claim 4. The axial extension controlling member is composed of a twisted wire obtained by twisting together a plurality of metal wire materials *(See, Specification at Page 15, lines 1-6).*

Claim 6 is directed to an indwelling implant as set forth in Claim 5. The axial extension controlling member is further twisted after insertion through the loop *(See, Specification at Page 15, lines 1-6).*

Claim 7 is directed to an indwelling implant as set forth in Claim 6. The coil is further formed to have a secondary shape *(See, Specification at Page 15, line 22 to Page 16, line 2).*

Claim 8 is directed to an indwelling implant for embolization including a coil composed of a metal and a substantially semi-spherical rounded head portion at the distal end portion of the coil *(See, Specification at Page 8, lines 9-24 and Page 4, lines 7-18).* A single closed loop is provided inside the coil from at least one of the distal end portion and proximal end portion of the coil toward the other end portion *(See, Specification at Figs. 1 and 2 and at Page 10, lines 1-5).* An axial extension controlling member composed of at least one wire material which is thinner than the metal wire material forming said loop is provided inside the coil by extending the member in the coil axial direction of the coil and fixing it inside the coil after the member passed through the loop *(See, Specification at Figs. 1 and 2, Page 10, lines 5-17 and Page 4, lines 19-27).* The single closed loop is directly fixed to the rounded head portion and directly coupled to the axial extension controlling member *(See, Specification at Figs. 1 and 2 and at Page 10, lines 1-5).*

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented on appeal are as follows:

(1) whether Claims 1-4 and 6-8 are unpatentable under 35 U.S.C. § 103(a) over Ken (US 6,013,084) in view of Bashiri (US 6,468,266) and Teoh (US 2004/0002732).

(2) whether Claim 5 is unpatentable under 35 U.S.C. § 103(a) over Ken in view of Bashiri, Teoh and Wilson (US 2004/0034363).

ARGUMENT

(1) Rejection of Claims 1-4 and 6-8 under 35 U.S.C. § 103(a) over Ken in view of Bashiri and Teoh

Claims 1 and 8

Independent Claim 1 is directed to an indwelling implant for embolization. In particular, Claim 1 recites "the [axial extension controlling] member passed through said loop" and "the single closed loop is directly fixed to the rounded head portion and directly coupled to the axial controlling member" and the axial extension controlling member "is thinner than the metal wire forming said loop". Independent Claim 8 similarly recites "the [axial extension controlling] member passed through said loop" and "the single closed loop is directly fixed to the rounded head portion and directly coupled to the axial extension controlling member" and the axial extension controlling member "is thinner than the metal wire material forming said loop."

Ken discloses a hook 199 that is indirectly (not directly) fixed to a head portion *(See, Ken at Fig. 10).* Hook 199 does not form a closed loop, but is merely an open-ended hook. In Ken, the coil 191 is the subject to be controlled by an axial extension controlling system. However, a coil different from coil 191 is provided between coil 191 and the hook 199 to control the axial extension. Bashiri teaches the same structure.

Bashiri discloses a hook 138 that is indirectly (not directly) fixed to a proximal end portion so as to control the extension through an interior anchor coil 136. Similar to Ken, hook 138 does not form a closed loop, and the coil 136 different from coil 120 is provided between coil 120 and the hook 138 to control the axial extension.

The Examiner's Answer dated April 23, 2009 includes a new ground of rejection directed to the Teoh reference where Teoh is asserted to teach applicant's single closed loop characterized by anchor chain 170 that is directly fixed to rounded

head portion 182. However, as disclosed in paragraph [0055] of Teoh, the anchor chain 170 includes two links, a proximal twisted link 172 and a distal twisted link 174. As shown in corresponding FIGs. 2C-2D, the proximal link 172 of anchor chain 170 is composed of a plurality of loops and does not form a single closed loop. At best, Teoh teaches an anchor chain 170 having a plurality of loops directly fixed to a ball 182. Thus, Teoh clearly does not remedy the deficiencies of Ken and Bashiri.

If the rejection is further clarified to assert that the ball 182 is directly fixed to a single loop (loop indicated by reference number 172) of the plurality of loops (anchor chain 170), Applicant submits that such interpretation is met only through the selective reading of Teoh without regards to the teachings of Teoh as a whole. Applicant notes that each reference must be considered as a whole for all that it teaches, including disclosure that teaches away from the claims *(See, M.P.E.P § 2141.02)*. Otherwise, the proposed modification is reached only through selective reading of the prior art with the impermissible hindsight afforded by applicant's disclosure. Ignoring disclosure within the references goes against the "teaching as a whole" requirement. The prior art must be considered for more than just what is necessary to reach applicant's invention.

In particular, paragraph [0056] teaches that the proximal link 172 of anchor chain 170 requires a closed loop 176 at its distal end, at least one twist/intersection 178 and a sealed junction 180 that connects the proximal end of link 172 to ball 182. Therefore, Teoh teaches that the proximal link 172 is necessarily a plurality of loops and cannot be conveniently construed as a single loop while disregarding the remaining loops in anchor chain 170 that are inconvenient to an obviousness analysis. Therefore, when Teoh is considered in its entirety, as a whole, the proximal link 172 must include a plurality of loops. Only through the impressible hindsight of applicant's disclosure would the use of just a single closed loop be suggested to one in the art. In view of the entire disclosure of Teoh, one of ordinary skill would directly fix the ball 182 to an anchor chain 170 having a plurality of loops and not to a single loop as recited in the claims.

Moreover, under the previous ground of rejection on page 3 of the Final Office Action, Teoh is asserted to teach an element that is a single closed loop which is directly fixed to a rounded head portion 107. However, Teoh instead discloses a stretch-resisting member 108 directly fixed to a head portion at a distal end portion thereof that acts to prevent axial stretching of the primary coil 102 *(See, Teoh at Fig. 1 and Paragraph [0041])*. Therefore, the loop disclosed by Teoh is merely an axial extension controlling member as shown in Fig. 2a. Thus, Teoh fails to disclose or suggest a distinct axial extension controlling member and loop, as required by independent Claims 1 and 8 of the present invention.

Furthermore, the assertion that the stretch-resisting member 108 of Teoh is a single closed loop disregards both the claimed invention and the cited references when considered as a whole. Again, Applicant notes that the prior art references must be considered in their entirety, as a whole, including disclosures that teach away from applicant's claims. The independent claims require the distinct components of a single closed loop, an axial extension controlling member and a rounded head portion. The rounded head is directly fixed to the single closed loop while the axial extension controlling member is directly coupled to the single closed loop. Importantly, since the axial extension controlling member is distinct and not the same as the single closed loop, the axial extension controlling member is coupled and passed through the closed loop. This feature is not possible if the axial extension controlling member includes the closed loop.

Teoh teaches, at best, that stretch-resisting member 108 includes a loop. However, any loop of stretch-resisting member 108 is clearly not applicant's distinct single closed loop fixed to both the rounded head portion and coupled to the axial extension controlling member. Clearly, the stretch-resisting member 108 cannot be both an axial extension controlling member and the loop as recited in Claims 1 and 8 because the axial extension controlling member must be passed through the single closed loop.

Furthermore, in the Advisory Action dated March 20, 2008, Teoh's teaching of a closed loop is cited in isolation without consideration of the context of the reference as a whole. Teoh teaches that stretch-resisting member 108 acts as an extension controlling member and such disclosure cannot be disregarded *(See, Teoh at Paragraph [0041]).*

Bashiri is further cited for teaching a loop thicker than an axial extension controlling member. But the loop of Bashiri is provided at more proximal side (not more distal end side) than the axial extension controlling member. In addition, in Figures, it seems that the axial extension controlling member is a little thinner than the loop. But such an action and effect is not explicitly described in the specification of Bashiri. Teoh teaches an axial extension controlling member including a loop. As pointed out by the Examiner, even if a difference of thickness of Bashiri is applied to the loop of Teoh, a purpose of the present invention can not be obtained. Because the loop of Teoh is an axial extension controlling member which should be thicker, and the whole of the coil becomes hard. Thus, the combination of Bashiri, Teoh and Ken makes no sense.

In contrast, the present invention as defined by independent Claims 1 and 8 requires that the axial extension controlling member pass through a single closed loop and for the single closed loop to be directly fixed to the rounded head portion and directly coupled to the axial extension controlling member, and that the axial extension controlling member is thinner than the loop. In this manner, an axial extension controlling member can be inserted and pulled through the loop to thereby fix the axial extension controlling member to the metal coil. Accordingly, this feature advantageously prevents the annealing-induced decrease in strength of the welded portion that occurs when the axial extension controlling member is directly welded to the distal end portion of the metal coil.

As stated at page 3, line 26 to page 4, line 5 of the present specification:

> ...when the extension controlling member was welded to the coil, the strength of the extension

> controlling member in the welded zone was greatly reduced by annealing. Therefore, the cross sectional area of the extension controlling member had to be sufficiently increased in order to obtain a strength necessary for the extension controlling member. The resultant problem was that flexibility of the indwelling implant for embolization was lost...

To achieve the advantages as described above, the loop is required to be directly fixed to a head portion and the loop to be connected to an extension controlling member which is thinner than the loop.

As pointed out above, the extension controlling member (loop 108) of Teoh is directly fixed to a head portion. Accordingly, unless the diameter of the fixed extension controlling member is enlarged, the problem of the strength cannot be resolved. But, if the diameter of the loop 108 is enlarged, the softness is damaged. Accordingly, Teoh cannot solve this problem. Because Teoh welds the stretch-resisting member 108 directly to the distal cap 107 in the same disadvantageous manner as described in Applicant's Specification, Teoh teaches against Applicant's stated purpose and thus provides no motivation or suggestion to combine Teoh with the applied references.

According to the present invention, a loop which is molded thicker than an axial extension controlling member is fixed to a head portion. The axial extension controlling member passes through the loop and does not require welding or heating in order to be fixed. Accordingly, as illustrated in Fig. 1, an axial extension controlling member is provided in an indwelling implant that is thinner and having sufficient softness to be maintained.

Hence, Teoh teaches away from any combination of Teoh, Ken and Bashiri, and there is no motivation to combine these three references. Applicant's insight is clearly contrary to the understandings and expectations of Teoh and Ken such that independent Claims 1 and 8 would not have been obvious to those skilled in the art.

Furthermore, as required by independent Claim 1 of the present invention, when the components provided to control the extension of the coil in the indwelling

implant, such as the head 12, loop 14, and axial extension controlling member 20 are provided respectively from the proximal side end to the distal side end portion, and a size of the coil and the loop are adjusted, a large extension in an axial direction of the indwelling implant for embolization can be prevented without any other coil differently from Bashiri, Teoh and Ken.

The ancillary references do not remedy the deficiencies of Ken. In particular, Wilson teaches a loop 34 which is directly attached to the coil 12 and not to distal end 14 *(See, Wilson at Abstract, Fig. 4 and Paragraph [0030]).*

Thus, the applied references do not disclose or suggest these features of the present invention as required by independent Claims 1 and 8.

Accordingly, independent Claims 1 and 8 are believed to be in condition for allowance.

Claims 2-4, 6 and 7

Claims 2-4, 6 and 7 depend either directly or indirectly from independent Claim 1 and recite additional features of the invention which are neither disclosed nor fairly suggested by the applied references and are therefore also believed to be in condition for allowance.

(2) Rejection of Claim 5 under 35 U.S.C. § 103(a) over Ken in view of Bashiri, Teoh and Wilson

Claim 5 depends indirectly from independent Claim 1 and recite additional features of the invention which are neither disclosed nor fairly suggested by the applied references and are therefore also believed to be in condition for allowance.

For these reasons, Applicant respectfully submits that Claims 1-8 are allowable over the art of record. An Appendix containing the appealed claims is attached, and the requisite fees for this Reply Brief and any applicable extensions or other fees due may be charged to our Deposit Account No. 50-1314.

Respectfully submitted,

HOGAN & HARTSON L.L.P.

Date: June 23, 2009

By: _____

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CLAIMS APPENDIX

1. (Previously presented): An indwelling implant for embolization comprising a coil composed of a metal and a substantially semispherical rounded head portion at the distal end portion of the coil, wherein a single closed loop is provided inside said coil from said head portion toward the proximal end portion of the coil, and an axial extension controlling member composed of at least one wire material which is thinner than the metal wire material forming said loop is provided inside said coil by extending the member in the coil axial direction of said coil and fixing both ends thereof directly or indirectly to the proximal end portion after the member passed through said loop,

wherein the single closed loop is directly fixed to the rounded head portion and directly coupled to the axial extension controlling member.

2. (Original): The indwelling implant for embolization according to claim 1, wherein the axial extension controlling member and loop are composed of the same metal material as the coil.

3. (Original): The indwelling implant for embolization according to claim 1 or 2, wherein the coil is composed of platinum or a platinum alloy.

4. (Previously Presented): The indwelling implant for embolization according to claim 3, wherein the axial extension controlling member is composed of a wire material with a diameter of 20 μm or less.

5. (Previously Presented): The indwelling implant for embolization according to claim 4, wherein the axial extension controlling member is composed of a twisted wire obtained by twisting together a plurality of metal wire materials.

6. (Previously Presented): The indwelling implant for embolization according to claim 5, wherein the axial extension controlling member is further twisted after insertion through the loop.

7. (Previously Presented): The indwelling implant for embolization according to claim 6, wherein the coil is further formed to have a secondary shape.

8. (Previously presented): An indwelling implant for embolization comprising a coil composed of a metal and a substantially semi-spherical rounded head portion at the distal end portion of the coil, wherein a single closed loop is provided inside said coil from at least one of the distal end portion and proximal end portion of the coil toward the other end portion, and an axial extension controlling member composed of at least one wire material which is thinner than the metal wire material forming said loop is provided inside said coil by extending the member in the coil axial direction of said coil and fixing it inside the coil after the member passed through said loop,

wherein the single closed loop is directly fixed to the rounded head portion and directly coupled to the axial extension controlling member.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.